

Food and Drug Administration, HHS

§ 1.393

development requires more than 4 calendar days to complete.

§ 1.384 When does a detention order terminate?

If FDA terminates a detention order or the detention period expires, an authorized FDA representative will issue a detention termination notice releasing the article of food to any person who received the detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags. If FDA fails to issue a detention termination notice and the detention period expires, the detention is deemed to be terminated.

HOW DOES FDA ORDER A DETENTION?

§ 1.391 Who approves a detention order?

An authorized FDA representative, *i.e.*, the FDA District Director in whose district the article of food involved is located or an FDA official senior to such director, must approve a detention order. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

§ 1.392 Who receives a copy of the detention order?

(a) FDA must issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

(b) If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA also must provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily.

§ 1.393 What information must FDA include in the detention order?

(a) FDA must issue the detention order in writing, in the form of a detention notice, signed and dated by the officer or qualified employee of FDA who has credible evidence or information indicating that such article of food presents a threat of serious adverse health consequences or death to humans or animals.

(b) The detention order must include the following information:

- (1) The detention order number;
- (2) The date and hour of the detention order;
- (3) Identification of the detained article of food;
- (4) The period of the detention;
- (5) A statement that the article of food identified in the order is detained for the period shown;
- (6) A brief, general statement of the reasons for the detention;
- (7) The address and location where the article of food is to be detained and the appropriate storage conditions;
- (8) Any applicable conditions of transportation of the detained article of food;
- (9) A statement that the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless the detention order is first modified under § 1.381(c);
- (10) The text of section 304(h) of the act and §§ 1.401 and 1.402;
- (11) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 1.403;
- (12) The mailing address, telephone number, e-mail address, and fax number of the FDA district office and the name of the FDA District Director in whose district the detained article of food is located;
- (13) A statement indicating the manner in which approval of the detention order was obtained, *i.e.*, verbally or in writing; and
- (14) The name and the title of the authorized FDA representative who approved the detention order.